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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,807

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Yaeta Endo

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KILYK & BOWERSOX, P.L.L.C.

400 HOLIDAY COURT

SUITE 102

WARRENTON, VA 20186

EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

03/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,807	Applicant(s) ENDO ET AL.	
	Examiner LISA V. COOK	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed 9/30/08 is acknowledged (Paper filed 12/22/08). In the amendment filed therein claims 1 and 11 were modified. Claim 10 was canceled. Currently claims 1-9 and 11-19 are pending and under consideration.
2. Objections and/or rejections of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-8 and 11-19 are rejected under 35 U.S.C. 103(a) as being obvious over Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of Hirth et al. (US Patent #5,763,198).

Sawasaki et al. teach a cell-free protein synthesis system. The system is based on the eukaryotic translation apparatus of wheat seeds and allows for the screening and synthesis of gene products. See abstract. Wheat embryos and cell-free extracts were purified. See page 14652-Materials.

In one instance protein products were tested as functional enzymes in the wheat cell free system. Four of five proteins displayed autophosphorylation activity after incubation with [γ -³²P]ATP and magnesium. See figure 5b.

Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) differ from the instant invention in not specifically teaching the inclusion of an indicator substance produced by an action induced by the trigger protein (or protein substrate).

However, Hirth et al. teach rapid and quantitative screening procedures to measure tyrosine kinase or phosphatase activity. The tyrosine phosphorylation state of a protein substrate is assessed by an anti-phosphotyrosine antibody (higher reactivity for phosphorylated substrate) and an antibody specific for the protein substrate (antibody with higher reactivity for unphosphorylated substrate).

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The bound complex is immobilized onto a solid support. See column 11 section 5.4 for example. The bound complex is labeled and detected (labeled substrate). See column 11 and 12 section 5.5. ELISA procedures are disclosed as one method of performing the detection. Column 3 through Column 4.

Hirth et al. disclose that this assay procedure offers several advantages including the evaluation of test substances in the natural context, it does not require redesign or the use of reagents for the particular kinase or phosphatase responsible for phosphorylating or dephosphorylating the substrate of interest, it does not require radioactive labeling of the target cell proteins, and it allows for the testing of large numbers of test samples within a reasonably short time frame. See column 5 line 57 through column 6 line 6.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to employ the antibodies (labels) with unphosphorylated substrate and phosphorylated substrate as taught by Hirth et al. in the method of Sawasaki et al. to measure protein kinase phosphorylation because Hirth et al. taught that his assay procedure offers several advantages including the evaluation of test substances in the natural context, it does not require redesign or the use of reagents for the particular kinase or phosphatase responsible for phosphorylating or dephosphorylating the substrate of interest, it does not require radioactive labeling of the target cell proteins, and it allows for the testing of large numbers of test samples within a reasonably short time frame. See column 5 line 57 through column 6 line 6.

II. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of Hirth et al. (US Patent #5,763,198) and further in view of Foster et al. (U.S. Patent #4,444,879).

Please see Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of Hirth et al. (US Patent #5,763,198) as set forth above.

Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of Hirth et al. (US Patent #5,763,198) differ from the instant invention in not specifically teaching kit configurations.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Sawasaki et al. (Proceedings of the National Academy of Sciences, USA Vol99, No.23, 11/12/02, pages 14652-14657) in view of Hirth et al. (US Patent #5,763,198) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit.

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Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

Response to Arguments

Applicant's amendments and arguments have been carefully considered and found persuasive. Accordingly the patent to Hirth et al. (US Patent #5,763,198) has been added to teach protein kinase substrate measurements.

4. For reasons aforementioned, no claims are allowed.

Remarks

5. Prior art of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Madin et al. (Proceedings of the National Academy of Sciences, USA Vol.97, No.2, 1/18/00, pages 559-564) disclose the isolation of wheat embryos.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Lisa V. Cook/
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